

IN THE CLAIMS

Claims 1-19 (Canceled).

20. (Currently amended) A stable pharmaceutical preparation comprising:

blood coagulation factor VII having a protease activity, when activated, of at least 50 U /mg of total protein, wherein blood coagulation factor preparation is free from blood coagulation inhibitors selected from the group consisting of benzamidine, soybean trypsin inhibitor and phenyl-methyl-sulfonyl fluoride, and contains no more than approximately 5% of activated blood coagulation factor VII.

21. (Currently amended) The stable pharmaceutical preparation of claim 20, wherein said the blood coagulation factor VII has a protease activity, when activated, of greater than 100 Units/mg of total protein.

22. (Currently amended) The stable pharmaceutical preparation of claim 20, wherein said the blood coagulation factor VII is present in an amount of between approximately 5 U/mL to approximately 5,000 U/mL.

23. (Currently amended) The stable pharmaceutical preparation of claim 20, wherein said the preparation is lyophilized.

24. (Currently amended) The stable pharmaceutical preparation of claim 23, wherein said the preparation is stable for at least 12 hours after reconstitution.

25. (Currently amended) The stable pharmaceutical preparation of claim 20, wherein said the blood coagulation factor VII is a recombinant protein.

26. (Currently amended) The stable pharmaceutical preparation of claim 20, wherein said the blood coagulation factor VII is recovered from normal human plasma.

27. (Currently amended) The stable pharmaceutical preparation of claim 26, wherein said the blood coagulation factor preparation has no detectable transmissible human pathogens.

28. (Currently amended) A method for preparing a stable pharmaceutical preparation comprising:

absorbing blood coagulation factor VII from a biological material onto a chromatographic substrate;

selectively eluting said the absorbed blood coagulation factor VII from said the chromatographic substrate using a ~~blood coagulation inhibitor free~~ an elution buffer that is free from blood coagulation inhibitors selected from the group consisting of benzamidine, soybean trypsin inhibitor and phenyl-methyl-sulfonyl fluoride; and

selecting an eluate having a protease activity of at least 50 U/mg of total protein, when activated, and

preparing the pharmaceutical preparation from the eluate, wherein the pharmaceutical preparation contains no more than approximately 5% activated blood coagulation factor VII and is free from blood coagulation inhibitors selected from the group consisting of benzamidine, soybean trypsin inhibitor and phenyl-methyl-sulfonyl fluoride.

29. (Currently amended) The method for preparing a stable pharmaceutical preparation of claim 28, wherein said the elution buffer has a pH of between approximately 5.0 to approximately 9.0.

30. (Currently amended) The method for preparing a stable pharmaceutical preparation of claim 29, wherein said the elution buffer has a pH of between approximately 6.0 to approximately 7.5.

31. (Currently amended) The method for preparing a stable pharmaceutical preparation of claim 28, wherein said the chromatographic substrate is an anion exchange material and said the selective elution being performed using a chromatography column and a chromatography column flow rate of at least 0.15 column volumes per minute.

32. (Currently amended) The method for preparing a stable pharmaceutical preparation of claim 31, wherein said the flow rate is between approximately 0.17 to 2.0 column volumes per minute.

33. (Currently amended) The method for preparing a stable pharmaceutical preparation of claim 28, wherein said the chromatographic substrate is an immunoaffinity column specific for factor VII.

34. (Currently amended) The method for preparing a stable pharmaceutical preparation of claim 28, wherein said the chromatographic substrate is a material having hydrophobic groups.

35. (Currently amended) The method for preparing a stable pharmaceutical preparation of claim 28, wherein said the chromatographic substrate is a hydrogel.

36. (Currently amended) The method for preparing a stable pharmaceutical preparation of claim 28, wherein said the biological material is selected from the group consisting of blood, plasma, a plasma fraction, a cell culture and a cell culture fraction.

37. (Currently amended) The method for preparing a stable pharmaceutical preparation of claim 31, further comprising absorbing said the eluate having a protease activity of at least 50 U/mg of total protein onto a second chromatographic substrate having hydrophobic groups and selectively eluting said the absorbed eluate from said the chromatographic substrate having hydrophobic groups.

38. (Currently amended) A stable pharmaceutical preparation made according to claim 28.

39. (Currently amended) A stable pharmaceutical preparation made according to claim 37.

40. (Currently amended) A stable pharmaceutical preparation comprising:

blood coagulation factor VII having a protease activity, when activated, of at least 50 U/mg of total protein, wherein said the blood coagulation factor preparation is free from blood coagulation inhibitors selected from the group consisting of benzamidine, soybean trypsin inhibitor and phenyl-methyl-sulfonyl fluoride, and contains no more than approximately 5% of activated blood coagulation factor VII ; and at least one additional coagulation factor.

41. (Currently amended) The stable pharmaceutical preparation of claim 40, wherein said the additional blood coagulation factor is selected from the group

consisting of factor II, factor IX and factor X.

42. (Currently amended) A method for preparing a stable pharmaceutical preparation comprising:

absorbing blood coagulation factor VII from a biological material onto an anionic chromatographic column;

selectively eluting said the absorbed blood coagulation factor VII from said the chromatographic column at a flow rate of between approximately 0.17 to 2.0 column volumes per minute using ~~a blood coagulation inhibitor free~~ an elution buffer having a pH of between approximately 6.0 to 7.5, wherein the elution buffer is free from blood coagulation inhibitors selected from the group consisting of benzamidine, soybean trypsin inhibitor and phenyl-methyl-sulfonyl fluoride; and

selecting an eluate having a protease activity of at least 50 U/mg of total protein, when activated, and

preparing the pharmaceutical preparation from the eluate, wherein the pharmaceutical preparation contains no more than approximately 5% activated blood coagulation factor VII and is free from blood coagulation inhibitors selected from the group consisting of benzamidine, soybean trypsin inhibitor and phenyl-methyl-sulfonyl fluoride.

43. (Currently amended) The method for preparing a stable pharmaceutical preparation of claim 42, wherein said the biological material is selected

from the group consisting of blood, plasma, a plasma fraction, a cell culture and a cell culture fraction.

44. (Currently amended) The method for preparing a stable pharmaceutical preparation of claim 42, further comprising absorbing said the eluate having a protease activity of at least 50 U/mg of total protein onto a second chromatographic substrate having hydrophobic groups and selectively eluting said the absorbed eluate from said the chromatographic substrate having hydrophobic groups.

45. (Currently amended) A stable pharmaceutical preparation made according to claim 42.

46. (Currently amended) A stable pharmaceutical preparation made according to claim 44.